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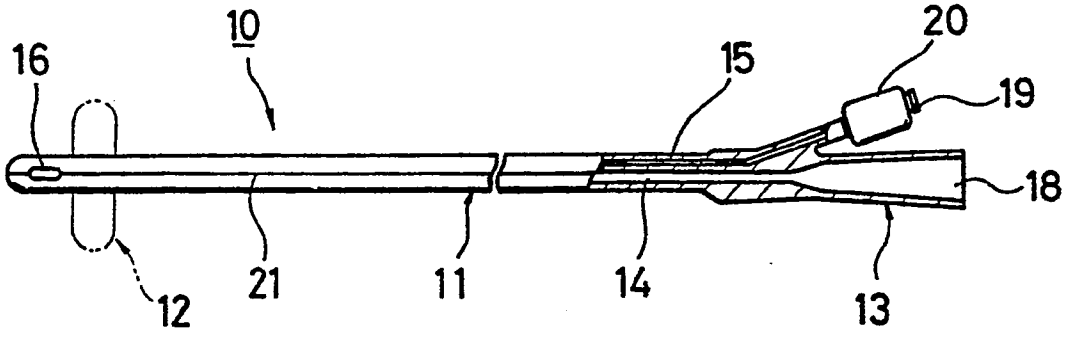
(54) Urethra catheter and manufacturing method therefor.

(57) A urethra catheter includes a shaft tube (11) having a main lumen (14) and a sub-lumen (15) and further having a urine inlet port (16) at the front end thereof, the urine inlet port being connected to the main lumen; a balloon (12) fastened on the outer surface of the front portion of the shaft tube to cover an opening portion of the sub-lumen formed in the shaft tube; and a base portion (13) disposed in the base end portion of the shaft tube, having a urine outlet port (18) connected to the main lumen, and further having a fluid inlet/outlet port (20) connected to the sub-lumen and capable of letting in or letting out fluid for expanding the balloon. Furtherly, the urethra catheter is characterized in that at least one of the shaft tube, the balloon, and the base portion is made of at least a material selected from groups consisting of polystyrene, polyolefine, polyurethane, and vinyl thermoplastic elastomers.

FIG.2



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URETHRA CATHETER AND MANUFACTURING METHOD THEREFOR

BACKGROUND OF THE INVENTION

The present invention relates to a urethra catheter disposed from the urethra to the urinary bladder and capable of conducting continuous urination and a manufacturing method therefor.

In general, urethra catheters are arranged to include: a shaft tube having a main lumen and a sub-lumen and further having a urine inlet port at the front portion thereof, the urine inlet port being connected to the main lumen; a balloon fastened on the outer surface of the front portion of the shaft tube to cover an opening portion of an air lumen formed in the shaft tube; and a base portion disposed in the base end portion of the shaft tube, having a urine outlet port connected to the main lumen, and further having a fluid inlet/outlet port connected to the sub-lumen and capable of letting in or letting out fluid for expanding the balloon.

Hitherto, a urethra catheter is arranged such that each of the above-described shaft tube, the above-described balloon, and the above-described base portion is made of latex rubber or silicone rubber.

However, the above-described urethra catheter made of lutex rubber is ① since a curing agent or the like is used, elution cannot be prevented, resulting a problem in terms of safety when it is used. Therefore, it is not suitable to be kept for a long time in the body of a patient who has been subjected to an operation. Furthermore, ② since the balloon is machined by dip molding, its wall thickness cannot be uniformed, causing a problem in terms of the machining facility.

Although elution can be reduced in the urethra catheter made of the above-described silicone rubber, a silicome type adhesive must be used for adhering the balloon to the shaft tube and adhering a cap for sealing the front end surface of the shaft tube. This deteriorates the machining facility. In addition, the elution from the adhesive taken place when the urethra catheter is kept in the body can deteriorate the safety when it is used.

An object of the present invention is to provide a urethra catheter exhibiting a safety when it is used and excellent manufacturing facility and a method therefor.

A urethra catheter in accordance with the present invention in claim 1 includes a shaft tube having a main lumen and a sub-lumen and further having a urine inlet port at the front end thereof, the urine inlet port being connected to the main lumen; a balloon fastened on the outer surface of the front portion of the shaft tube to cover an opening portion of the sub-lumen formed in the shaft tube; and a base portion disposed in the base end portion of the shaft tube, having a urine outlet port connected to the main lumen, and further having a fluid inlet/outlet port connected to the sub-lumen and capable of letting in or letting out fluid for expanding the balloon, the urethra catheter being characterized in that: at least one of the shaft tube, the balloon, and the base portion is made of at least a material selected from groups consisting of polystyrene, polyolefine, polyurethane, and vinyl thermoplastic elastomers.

A urethra catheter in according with the present invention in Claim 2 is that the shaft tube and the balloon are respectively made of a material selected from the groups.

A urethra catheter in according with the present invention in Claim 3 is that the shaft tube and the balloon are made of the same material selected from the groups.

A urethra catheter in according with the present invention in Claim 4 is that the shaft tube and the balloon are made of the polystyrene thermoplastic elastomer.

A urethra catheter in according with the present invention in Claim 5 is that the shaft tube, the balloon, and the base portion are respectively made of at least a material selected from the groups.

A urethra catheter in according with the present invention in Claim 6 is that the shaft tube, the balloon, and the base portion are made of the same material selected from the groups.

A urethra catheter in according with the present invention in Claim 7 is that the shaft tube, the balloon, and the base portion are made of the polystyrene thermoplastic elastomer.

A method of manufacturing a urethra catheter in accordance with the present invention in Claim 8 comprises the manufacturing processes of: a manufacturing process in which the shaft tube is manufactured and the balloon is manufactured; a manufacturing process in which the balloon is fastened to cover the outer portion of the front portion of the shaft tube, and then the both end portions of the balloon are heated so as to be welded to the shaft tube; a manufacturing process in which the base portion is formed in the base end portion of the shaft tube; and a manufacturing process in which the front portion of the shaft tube is machined.

A method of manufacturing a urethra catheter in according with the present invention in Claim 9 is that

the manufacturing process in which the shaft tube is manufactured consists of a manufacturing process in which the shaft tube is extrusion-molded, a manufacturing process in which the shaft tube is cut so as to have a predetermined length, a manufacturing process in which the front portion of the shaft tube is reduced in its diameter by a predetermined size, and a manufacturing process in which an opening portion connected to the sub-lumen is formed in the front end portion whose diameter has been reduced.

A method of manufacturing a urethra catheter in according with the present invention in Claim 10 is that the manufacturing process in which the balloon is manufactured consists of extrusion-molding work or injection-molding work.

A method of manufacturing a urethra catheter in according with the present invention in Claim 11 is that the manufacturing process in which the balloon is welded to the shaft tube is conducted in such a manner that a heated mold isbrought into contact with the both end portions of the balloon and the wire core is rotated on condition that the balloon is welded to the outer portion of the front end portion of the shaft tube and a wire core is inserted into the main lumen of the shaft tube so that the welding isconducted.

A method of manufacturing a urethra catheter in according with the present invention in Claim 12 is that the manufacturing process in which the base portion is formed at the base end portion of the shaft tube is conducted in such a manner that the base portion is formed by insert-molding in the shaft tube.

A method of manufacturing a urethra catheter in according with the present invention in Claim 13 is that the manufacturing process in which the base portion is formed at the base end portion of the shaft tube is conducted in such a manner that the base portion manufactured by injection molding is welded with heat to the base end portion of the shaft tube.

A method of manufacturing a urethra catheter in according with the present invention in Claim 14 is that the manufacturing process in which the front portion of the shaft tube is machined is conducted in such a manner that a semispherical outer surface in which the main lumen and the sub-lumen are closed is formed by the manufacturing process in which an opening portion connected to the main lumen is formed in the portion more forward than the balloon of the shaft tube and by mold-machining the front end surface of the shaft tube with heat.

A method of manufacturing a urethra catheter in accordance with the present invention in Claim 15 is that the manufacturing process in which the balloon is welded to the shaft tube is conducted in such a manner that the front end portion of the balloon to be welded to the shaft tube is arranged to have a larger size than another end portion of the balloon to be welded to the shaft tube.

[Effects]

① According to the present invention disclosed in Claim 1, at least any of the shaft tube, the balloon, and the base portion is formed by thermoplastic elastomer. Since the thermoplastic elastomer does not use a curing agent and must not use an adhesive due to its welding performance, there is no fear of elution to be taken place when it is kept in the body, causing for the urethra catheter to be used safely.

② According to the present invention disclosed in Claim 2, the shaft tube and the balloon inserted to the body are made of the thermoplastic elastomer. Therefore, there is no fear of elution from the outer surface of the components which are brought into contact with the human's body. Therefore, the urethra catheter can be used further safely.

③ According to the present invention disclosed in Claim 3, the shaft tube and the balloon to be inserted into the body are formed by the same type thermoplastic elastomer. Therefore, the shaft tube and the balloon can be easily welded to each other because they are made of the same material in addition to the effect described in ②.

④ According to the present invention disclosed in Claim 4, the shaft tube and the balloon to be inserted into the body are formed by the polystyrene thermoplastic elastomer. Therefore, excellent chemical resistance can be obtained in addition to the effect described in ③.

⑤ According to the present invention disclosed in Claim 5, the overall body (except for a valve and a fixing rubber. Since the valve and the fixing rubber are connected to the sub-lumen, they do not relate to the outer surface and the main lumen through which urene passes) is made of the thermoplastic elastomer. Therefore, there is no fear of elution to take place in both the outer surfaces of the components which are brought into contact with the human's body and the main lumen through which urene passes. Therefore, the urethra catheter can be used extremely safely.

⑥ According to the present invention disclosed in Claim 6, the overall body is made of the same thermoplastic elastomer. Therefore, welding of the components can be esaily conducted since they are made of the same material in addition to the effect described in 5.

⑦ According to the present invention disclosed in Claim 7, the overall body is made of the polystyrene thermoplastic elastomer. Therefore, excellent chemical resistance can be obtained in addition to the effect described in ⑥.

⑧ According to the present invention disclosed in Claim 8, the components are respectively formed and assembled by a molding method utilizing the characteristics of the thermoplastic elastomer and by a welding method utilizing heat. Therefore, a urethra catheter exhibiting excellent dimension and appearance can be manufactured without a necessity of using an adhesive. Furthermore, excellent machining facility can be realized.

⑨ According to the present invention disclosed in Claim 9, the front end portion of the shaft tube is reduced in its diameter (by a size corresponding to the thickness of the balloon) before the balloon is welded to the portion whose diameter has been reduced. Therefore, the diameter of the portion to which the balloon is fastened and the diameter of the other portions can be made the same, causing any step to be eliminated. As a result, resistance taken place when the urethra catheter is inserted into the body can be reduced.

⑩ According to the present invention disclosed in Claim 10, the balloon is formed by extrusion molding or injection molding. Therefore, a balloon having a stable thickness can be provided.

⑪ According to the present invention disclosed in Claim 11, the wire core inserted into the main lumen of the shaft tube is rotated on condition that the both end portions of the balloon fastened to cover the outer surface of the front portion of the shaft tube are positioned in contact with a heated mold. Therefore the balloon can be welded to the shaft tube assuredly and uniformly.

⑫ According to the present invention disclosed in Claim 12, since the base portion is insert-molded to the shaft tube, the base portion can be fastened assuredly.

⑬ According to the present invention disclosed in Claim 13, the base portion manufactured by injection molding is welded to the base end portion of the shaft tube with heat. Therefore, working efficiency can be improved.

⑭ According to the present invention disclosed in Claim 14, since the front end surface of the shaft tube is molded with heat, the front end surface of the shaft tube can be finished uniformly and equally. Therefore, the front end surface can be sealed.

⑮ According to the present invention disclosed in Claim 15, the machining of the front end portion of the shaft tube can be easy.

BRIEF DESCRIPTION OF DRAWINGS

Fig. 1 is a view which illustrates the appearance of urethra catheter according to an embodiment of the present invention,

Fig. 2 is a cross sectional view which illustrate an essential portion of the urethra catheter shown in Fig. 1,

Fig 3 is a cross sectional view which illustrates the balloon portion shown in Fig. 1,

Fig. 4 is a cross-sectional view which illustrates the shaft tube portion shown in Fig. 1, and

Fig. 5 is a flow chart which illustrates the method of manufacturing the urethra catheter.

A urethra catheter 10 is, as shown in Figs. 1 and 2, constituted by a shaft tube 11, a balloon 12, and a base portion 13.

As shown in Figs. 3 and 4, the shaft tube 11 has a main lumen 14, a sub-lumen 15, and a urine inlet port 16 connected to the main lumen 14, the urine inlet port 16 being formed in the side surface of the front portion thereof.

The balloon 12 is secured around an opening 17 on the outer surface of the front portion of the shaft tube 11, the opening 17 being formed in the sub-lumen 15 provided for the shaft tube 11.

A base portion 13 is disposed adjacent to the base end portion of the shaft tube 11 and has a urine outlet port 18 connected to the main lumen 14, the base portion 13 further having a valve 19 (fluid inlet/outlet port) connected to the sub-lumen 15 and capable of letting in or letting out fluid which acts to expand the balloon. The valve 19 is fastened to the end portion of the base portion 13, and the state of the fastening is fixed by a fixing rubber 20.

Te urethra catheter 10 is used in such a manner that a urine outlet tube connected to a urine accumulating bag is connected to the urine outlet port 18. As a result, urine introduced through the urine inlet port 16 formed in the shaft tube 11 can be eliminated through the main lumen 14 and the urine outlet port 18. The balloon 12 is expanded when fluid for expanding the balloon such as sterilized water injected by a syringe inserted into the valve 19 is supplied through the sub-lumen 15.

The urethra catheter 10 has a contrast media line 21 formed on the surface of its shaft tube 11 in the direction of its axis.

The urethra catheter 10 can employ thermoplastic elastomers defined by the following groups (A) to (D) as the materials for its shaft tube 11, the balloon 12, and the base portion 13.

(A) Polystyrene thermoplastic elastomer

For example, SEBS (Styrene-Ethylene-Butylene-Styrene), SBS (Styrene-Butadiene-Styrene), SIS (Styrene-Isoprene-Styrene)

Preferable SEBS is exemplified by "RABALON" (trade name) manufactured by Mitsubishi Petro-Chemical Co., Ltd.

(B) Polyolefine thermoplastic elastomer

For example, partially crosslinked polyolefine thermoplastic elastomer such as EPBM-polyethylene and butyl rubber-polypropylene

(C) Polyurethane thermoplastic elastomer

For example, polyurethance, polyurethane-polyol

(D) Vinyl thermoplastic elastomer

For example, vinyl acetate thermoplastic elastomer, polyvinyl chloride thermoplastic elastomer

In this case, the urethra catheter 10 is specifically constituted in a manner selected from the following manners (1) to (7).

(1) At least one of the shaft tube 11, the balloon 12, and the base portion 13 is made of a material selected from the above-described groups.

(2) The shaft tube 11 and the balloon 12 are respectively made of a material selected from the above-described groups.

(3) The shaft tube 11 and the balloon 12 are made of the same material selected from the above-described groups.

(4) The shaft tube 11 and the balloon 12 are made of the above-described polystyrene thermoplastic elastomer.

(5) The shaft tube 11, the balloon 12 and the base portion 13 are respectively made of at least a material selected from the above-described groups.

(6) The shaft tube 11, the balloon 12, and the base portion 13 are made of the same material selected from the above-described groups.

(7) The shaft tube 11, the balloon 12, and the base portion 13 are made of the above-described polystyrene thermoplastic elastomer.

Then, a method of manufacturing the above-described urethra catheter 10 will be described.

The urethra catheter 10 is manufactured by a method selected from the following manufacturing processes (1) to (6) (see Fig. 5):

(1) A process in which the shaft tube 11 is manufactured (steps ①, ②, and ③).

This manufacturing process specifically consists of a manufacturing process (step ①) in which ⓐ the shaft tube 11 is extrusion-molded, and the shaft tube 11 is cut so as to have a predetermined length (6, 8Fr must have a length of 280 mm, while 10 to 26Fr must have a length of 370 mm), a manufacturing process (step ②) in which ⓑ the diameter of the front portion of the shaft tube 11 is reduced to have a predetermined diameter (1) by using a heated sizing die 101, and a manufacturing process (step ③) in which ⓒ the opening 17 connected to the above-described sub-lumen 15 is formed in the front end portion whose diameter has been reduced by the predetermined diameter.

The diameter obtained by the reduction must be arranged to be substantially the same as the wall thickness of the balloon 12 to be described later. As a result, the shaft tube 11 does not generate a step between the portion to which the balloon is fastened and the other portions.

(2) A manufacturing process in which the balloon 12 is manufactured (step ④)

This manufacturing process is a process in which the balloon 12 is extrusion-molded or injection-molded, and the balloon 12 thus molded is cut to have a predetermined length (15 to 21 mm).

It is preferable that the length obtained by cutting be similar to the predetermined diameter 1 of the shaft tube 11 obtained by the diameter reduction.

The wall thickness of the balloon 12 is 0.4 mm.

(3) A manufacturing process in which the balloon 12 is disposed to cover the outer surface of the front portion of the shaft tube 11, and the two sides of the balloon 12 are heated so as to be welded to the shaft tube (step ⑤).

This process is a process in which the balloon 12 is caused to cover the outer surface of the front portion of the shaft tube 11 (it is preferable that the front portion is the front end portion whose diameter has been reduced by the predetermined diameter), and a wire core 102 is inserted into the main lumen 14 of the shaft tube 11. In this state, the both end portions of the balloon 12 are brought into contact with the surfaces of recessed portions of a mold 103 whose both end portions are heated and made of, for example, brass before the wire core 102 is rotated. Thus, the two end portions of the balloon 12 are welded to the shaft tube 11 by an external heat application method (a method in which it is heated from outside by using a heater).

It is preferable that the front end portion of the portion to be welded be arranged to have a larger size in terms of easiness in conducting the machining of the front end portion to be described later.

The surfaces of the recessed portions of the mold 103 is subjected to Teflon coating. The mold 103 is heated up to about 240 ° C by a heater.

The balloon 12 may be welded to the shaft tube 11 by an internal heat application method. The internal heat application method is a method in which a subject to be heated is placed in a coil to which high frequency current is being supplied so as to cause the subject to generate heat. With this method, heating can be conducted uniformly.

(4) A manufacturing process (step ⑥) in which the base portion 13 is formed at the base end portion of the shaft tube 11

This manufacturing process is a process in which the base portion 13 is molded so as to be the shaft tube 11 by insert molding.

Another aspect of this process may be employed in which only the base portion 13 is previously manufactured, and this base portion 13 is welded by heat generated by high frequency welding to the base portion of the shaft tube 11.

(5) A manufacturing process (steps ⑦ and ⑧) in which the front portion of the shaft tube 11 is machined

Specifically, this process consists of a manufacturing process (step ⑦) in which ⓐ a slight quantity of silicone oil is applied to the front portion of the shaft tube 11, and this front portion is urged to be inserted into a cylindrical glass mold 104 (or a mold) having a bottom and whose front end portion has been heated, this front portion being inserted with being rotated. As a result, the front portion is sealed so as to form a round shape by utilizing the thermoplasticity of the raw material, and a munufacturing process (step ⑧) in which ⓑ a urine inlet port 16 (side hole) connected to the main lumen 14 is formed in a portion which is positioned forward than the position of the balloon 12 of the shaft tube 11. As a result, a semispherical outer portion in which the main lumen 14 and the sub-lumen 15 are closed is formed at the front portion of the shaft tube 11.

(6) A manufacturing process (step ⑨) in which the valve 19 is fastened to the base portion 13

The valve 19 is fastened to the end portion of the base portion 13, and the fastening is fixed by a fixing rubber 20.

Then, the effects of the urethra catheter 10 will be described.

① In the case where at least any of the shaft tube 11, the balloon 12, and the base portion 13 is made of thermoplastic elastomer, the urethra catheter 10 can be used safely even if it is kept in the body because there is no fear of elution since no curing agent is used in the thermoplastic elastomer, and the same has a welding performance, causing the necessity of using an adhesive to be eliminated.

② In the case where the shaft tube 11 and the balloon 12 to be inserted into the body are made of thermoplastic elastomer, there is no fear of elution from the outer surface of the elements which are brought into contact with the human's body. Therefore, it can be used safely.

③ In the case where the shaft tube 11 and the balloon 12 to be inserted into the body are made of

the same thermoplastic elastomer, they can be easily welded to each other since they are made of the same material in addition to the effect described in ②.

④ In the case where the shaft tube 11 and the balloon 12 to be inserted into the body are made of polystyrene thermoplastic elastomer, excellent chemical resistance is exhibited in addition to the effect described in③.

⑤ In the case where overall body of the shaft tube 11, the balloon 12, and the base portion 13 (except for the valve 19 and the fixing rubber 20. Since the valve 19 and the fixing rubber 20 are connected to the sub-lumen 15, they have no relationship with the outer surface and the main lumen 14 through which urine passes) are made of thermoplastic elastomer, there is no fear of elution from both the outer surface other than the portion of the components to be brought into contact with the human's body and the main lumen 14 through which urine passes. Therefore, the urethra catheter 10 can be used extremely safely.

⑥ In the case where overall body of the shaft tube 11, the balloon 12, and the base portion 13 are made of the same thermoplastic elastomer, they can be easily welded to each other since they are made of the same material in addition to the effect described shown in ⑤.

⑦ In the case where overall body of the shaft tube 11, the balloon 12, and the base portion 13 are made of polystyrene thermoplastic elastomer, excellent chemical resistance is exhibited in addition to the effect described in⑥.

Then, the effects of the manufacturing method of the above-described urethra catheter 10 will be described.

⑧ Since each of the components is formed and assembled with a molding method utilizing the characteristics of the thermoplastic elastomer and a heat welding method, the urethra catheter 10 exhibiting good dimension and appearance can be manufactured without use of an adhesive, and a satisfactory machining facility can be realized.

⑨ The diameter of the front portion of the shaft tube 11 is reduced (by a size corresponding to the thickness of the balloon 12) so as to weld the balloon 12 to the thus size-reduced portion. As a result, the diameter of the portion to which the balloon 12 is fastened and the diameter of the other portion can be made the same, causing any step to beeliminated. Therefore, resistance caused at the time of the insertion can be reduced.

⑩ Since the balloon 12 is manufactured by extrusion molding or injection molding, the balloon 12 having a stable thickness can be provided.

⑪ Since the wire core 102 inserted into the main lumen 14 of the shaft tube 11 is rotated in a state where both end portions of the balloon 12 fastened to cover the outer surface of the front portion of the shaft tube 11 are positioned to contact with the heating mold 103, the balloon 12 can be welded to the shaft tube 11 in an assured and uniform manner.

⑫ Since the base portion 13 is insert-molded to the shaft tube 11, the fastening of the base portion 13 can be conducted assuredly.

⑬ Since the base portion 13 manufactured by injection molding is welded to the base end portion of the shaft tube 11 by utilizing heat, the working efficiency can be improved.

⑭ Since the front end portion of the shaft tube 11 is molded by the glass mold 104 with heat applied thereto, the surface of the front portion of the shaft tube 11 can be finished uniformly and equally so that this front end surface can be sealed.

⑮ Since the front end portion of the balloon 12 to be welded to the shaft tube 11 is arranged to have a larger size than another end portion of the balloon 12 to be welded to the shaft tube 11, the machining of the front end portion of the shaft can be easy.

Table 1 shows the results of experiments carried out to evaluate elution taken place in each of the urethra catheters according to the present invention and comparative examples.

Symbol (A) according to the present invention represents a sample employing polystyrene thermoplastic elastomer as its material, while Embodiments 1, 2, and 3 were made of SEBS, SBS, and SIS, respectively.

Symbol (B) according to the present invention represents a sample employing polyolefine elastomer as its material, while Embodiments 4 and 5 were made of partially crosslinked EPDM-polyethylene and butyl rubber-polypropylene, respectively.

Symbol (C) according to the present invention represents a sample employing polyurethane thermoplastic elastomer as its material, while Embodiments 6 and 7 were made of polyurethane-polyester and polyurethane-polyol, respectively.

Symbol (D) according to the present invention represents a sample employing vinyl thermoplastic elastomer as its material, while Embodiments 8 and 9 were made of ethylene-vinyl acetate and polyvinyl chloride elastomers, respectively.

The test methods for evaluating $\Delta KMnO_4$ and ΔPH factors were conducted in accordance with rubber

test method with a disposable blood transfusion set and fluid transfusion method. The test method for evaluating UV absorbancy was conducted in such a manner that absorbance was measured under conditions that the layer length was 10 mm and wavelength was 220 nm by using test fluid according to the above-described rubber test method and novel test fluid serving as a reference. The factor of UV absorbance was conducted so as to measure the absorbancy of ultraviolet rays (220 nm) displayed by the test fluid. It means that the smaller the absorbance becomes, the more the portion in which the elution occurs can be reduced.

As is shown from Table 1, according to the present invention, the quantity of elution can be reduced satisfactorily with respect to the case in which silicone rubber is employed. Furthermore, safety when it is used can be realized.

As described above, according to the present invention, urethra catheter exhibiting excellent safety when it is used use and satisfactory wording facility can be obtained.

Table 1

			$\Delta KMnO_4$ ml	ΔPH	UV Absorbance 220 nm Abs	
Examples of the present invention	A	Embodiment 1	0.02	0.21	0.004	Absorvance of the test fluid according to the $\Delta KMnO_4$ and ΔPH tests and the same of test fluid which had not been subjected to any test were measured under condition that the layer length was 10mm and the wavelength was 220nm
		Embodiment 2	0.03	0.20	0.004	
		Embodiment 3	0.02	0.21	0.005	
	B	Embodiment 4	0.02	0.20	0.004	
		Embodiment 5	0.04	0.21	0.004	
	C	Embodiment 6	0.03	0.23	0.003	
		Embodiment 7	0.03	0.22	0.003	
	D	Embodiment 8	0.02	0.21	0.005	
		Embodiment 9	0.03	0.22	0.003	
Comparative Example 1			0.50	0.29	0.292	
Comparative Example 2			0.10	0.21	0.005	
Test Method			According to rubber test method based on disposable blood transfusion set and fluid transfusion set			

Claims

(1) A urethra catheter including: a shaft tube having a main lumen and a sub-lumen and further having a urine inlet port at the front end thereof, said urine inlet port being connected to said main lumen; a balloon

fastened on the outer surface of the front portion of said shaft tube to cover an opening portion of said sub-lumen formed in said shaft tube; and a base portion disposed in the base end portion of said shaft tube, having a urine outlet port connected to said main lumen, and further having a fluid inlet/outlet port connected to said sub-lumen and capable of letting in or letting out fluid for expanding said balloon, said urethra catheter being characterized in that: at least one of said shaft tubes, said balloon, and said base portion is made of at least a material selected from groups consisting of polystyrene, polyolefine, polyurethane, and vinyl thermoplastic elastomers.

(2) A urethra catheter according to Claim 1, wherein said shaft tube and said balloon are respectively made of a material selected from said groups.

(3) A urethra catheter according to Claim 1, wherein said shaft tube and said balloon are made of the same material selected from said groups.

(4) A urethra catheter according to Claim 3, wherein said shaft tube and said balloon are made of said polystyrene thermoplastic elastomer.

(5) A urethra catheter according to Claim 1, wherein said shaft tube, said balloon, and said base portion are respectively made of at least a material selected from said groups.

(6) A urethra catheter according to Claim 1, wherein said shaft tube, said balloon, and said base portion are made of the same material selected from said groups.

(7) A urethra catheter according to Claim 6, wherein said shaft tube, said balloon, and said base portion are made of said polystyrene thermoplastic elastomer.

(8) A method of manufacturing a urethra catheter according to Claim 1 and comprising the manufacturing processes of: a manufacturing process in which said shaft tube is manufactured and said balloon is manufactured; a manufacturing process in which said balloon is fastened to cover said outer portion of said front portion of said shaft tube, and then the both end portions of said balloon are heated so as to be welded to said shaft tube; a manufacturing process in which said base portion is formed in said base end portion of said shaft tube; and a manufacturing process in which said front portion of said shaft tube is machined.

(9) A method of manufacturing a urethra catheter according to Claim 8, wherein said manufacturing process in which said shaft tube is manufactured consists of a manufacturing process in which said shaft tube is extrusion-molded, a manufacturing process in which said shaft tube is cut so as to have a predetermined length, a manufacturing process in which said front portion of said shaft tube is reduced in its diameter by a predetermined size, and a manufacturing process in which an opening portion connected to said sub-lumen is formed in said front end portion whose diameter has been reduced.

(10) A method of manufacturing a urethra catheter according to Claim 8, wherein said manufacturing process in which said balloon is manufactured consists of extrusion-molding work or injection-molding work.

(11) A method of manufacturing a urethra catheter according to Claim 8, wherein said manufacturing process in which said balloon is welded to said shaft tube is connected in such a manner that a heated mold is brought into contact with said both end portions of said balloon and said wire core is rotated on condition that said balloon is welded to said outer portion of said front end portion of said shaft tube and a wire core is inserted into said main lumen of said shaft tube so that said welding is conducted.

(12) A method of manufacturing a urethra catheter according to Claim 8, wherein said manufacturing process in which said base portion is formed at said base end portion of said shaft tube is conducted in such a manner that said base portion is formed by insert-molding in said shaft tube.

(13) A method of manufacturing a urethra catheter according to Claim 8, wherein said manufacturing process in which said base portion is formed at said base end portion of said shaft tube is conducted in such a manner that said base portion manufactured by injection molding is welded with heat to said base end portion of said shaft tube.

(14) A method of manufacturing a urethra catheter according to Claim 8, wherein said manufacturing process in which said front portion of said shaft tube is machined is conducted in such a manner that a semispherical outer surface in which said main lumen and said sub-lumen are closed is formed by said manufacturing process in which an opening portion connected to said main lumen is formed in the portion more forward than said balloon of said shaft tube and by mold-machining the front end surface of said shaft tube with heat.

(15) A method of manufacturing a urethra catheter according to Claim 8, wherein said manufacturing process in which said balloon is welded to said shaft tube is conducted in such a manner that said front end portion of said balloon to be welded to said shaft tube is arranged to have a larger size than another end portion of said balloon to be welded to said shaft tube.

FIG.1

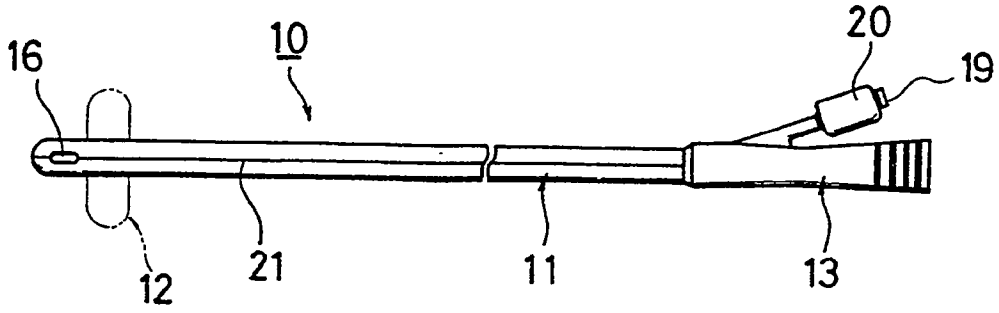


FIG.2

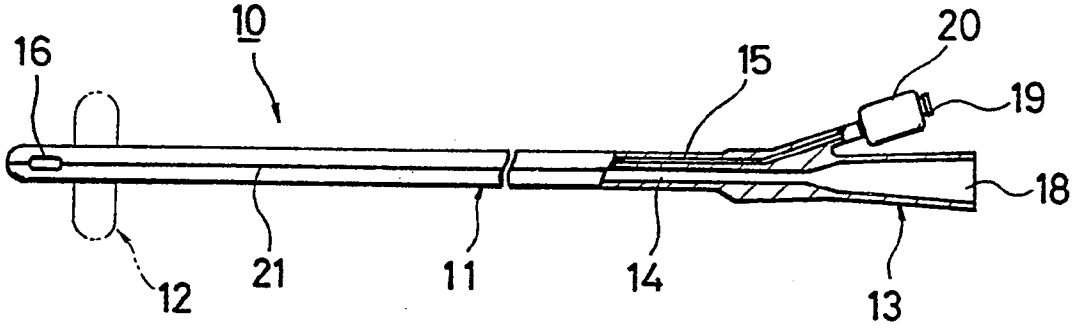


FIG.3

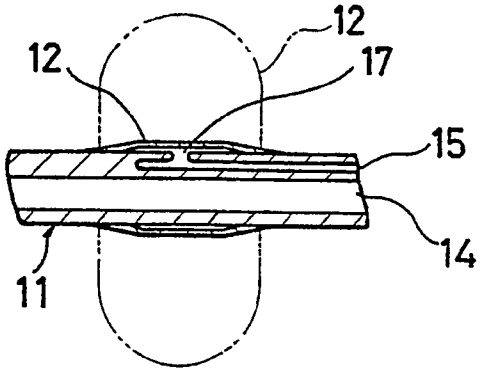


FIG.4

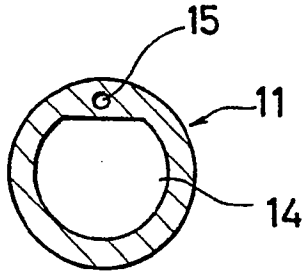
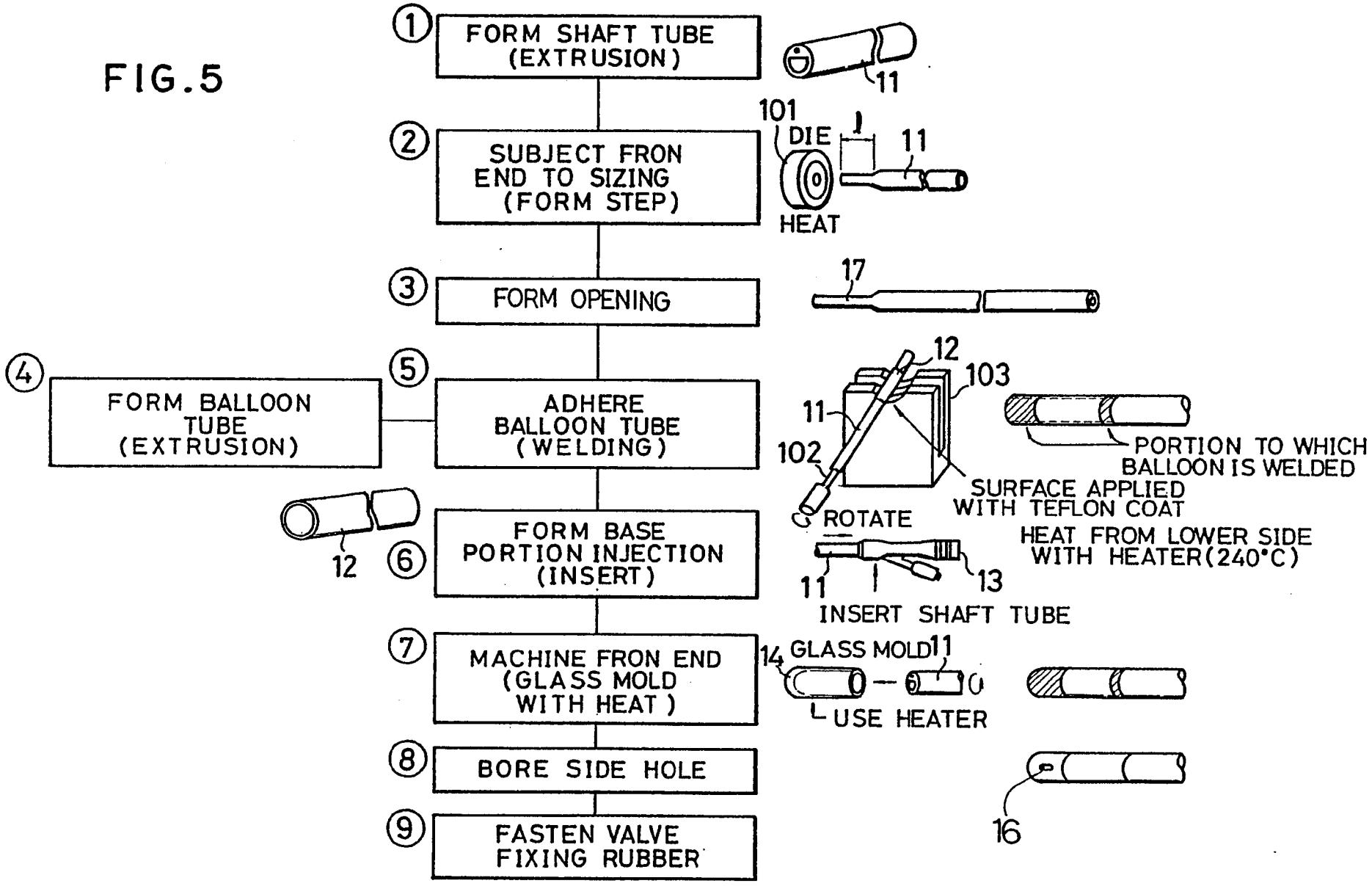


FIG.5


① FORM SHAFT TUBE (EXTRUSION)
11
② SUBJECT FRON END TO SIZING (FORM STEP)
101
DIE
11
HEAT
③ FORM OPENING
17
④ FORM BALLOON TUBE (EXTRUSION)
⑤ ADHERE BALLOON TUBE (WELDING)
12
103
11
102
PORTION TO WHICH BALLOON IS WELDED
SURFACE APPLIED WITH TEFLON COAT
ROTATE
HEAT FROM LOWER SIDE WITH HEATER(240°C)
12
⑥ FORM BASE PORTION INJECTION (INSERT)
11
13
INSERT SHAFT TUBE
⑦ MACHINE FRON END (GLASS MOLD WITH HEAT)
14
GLASS MOLD
11
USE HEATER
⑧ BORE SIDE HOLE
16
⑨ FASTEN VALVE FIXING RUBBER

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 89 12 2072

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X	FR-A-2 371 933 (THE KENDALL CO.) * Page 2, line 34 - page 6, line 23; page 7, lines 30-38 *	1-7	A 61 M 25/00
A	---	8-15	
X	GB-A-1 428 766 (W. OGLEY) * Claims 1-7 *	1-3,5-6	
A	-----	9	

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A 61 M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	06-03-1990	MIR Y GUILLEN V.

CATEGORY OF CITED DOCUMENTS

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